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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/059,929 | 01/29/2002 | Tuan Bui | EIP-5807 (1417G P 678) | 8386 |
| 29200 | 7590 | 09/26/2006 | | EXAMINER |
| BAXTER HEALTHCARE CORPORATION 1 BAXTER PARKWAY DF2-2E DEERFIELD, IL 60015 | | | COBANOGLU, DILEK B | |
| | | | ART UNIT | PAPER NUMBER |
| | | | | 3626 |

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/059,929 | BUI ET AL. | |
| | Examiner | Art Unit | |
| | Dilek B. Cobanoglu | 3626 | |

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 29 January 2002.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-191 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-191 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>05/30/2002, 8/23/2004, 8/24/2004</u> | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-191 have been examined.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-5, 7-11, 14-24, 26-29, 32-34, 36-40, 41-44, 45-49, 51-55, 58-71, 73-77, 80-91, 93-103, 106-110, 113-118, 120-124, 126-137, 139-150, 152-154, 160-162, 164-170, 172-178, 180-187 and 189-191 are rejected under 35 U.S.C. 102(e) as being unpatentable by Greene et al. (hereinafter Greene) (U.S. Patent No. 7,051,120 B2).

A. As per claim 1, Greene discloses a method for operating a medical device, the method comprising the steps of:

- i. inputting into a first computer a first patient identifier and an operating parameter for the medical device (Greene; col. 1, lines 46-63, col. 2, lines 5-32);
- ii. inputting into a second computer, from a first source, a second patient identifier (Greene; col. 1, lines 54-63, col. 2, lines 56-63);

- iii. inputting into the second computer, from a second source, a medication identifier, the medication identifier including a third patient identifier (Greene; col. 6, lines 6-23, col. 14, lines 13-30);
- iv. sending the medication identifier to the first computer, if the second patient identifier is equivalent to the third patient identifier (Greene; col. 11, lines 40-51, col. 14, lines 13-30); and
- v. sending the operating parameter from the first computer to the medical device, if the third patient identifier is equivalent to the first patient identifier, where the operating parameter does not pass through the second computer (Greene; col. 11, line 57 to col. 12, line 18).

B. As per claim 2, Greene discloses the method of claim 1, further comprising the step of: inputting into the first computer a second medication identifier, where the step of sending the operating parameter to the medical device is performed only if the first and second medication identifiers are equivalent (Greene; col. 11, line 57 to col. 12, line 5).

C. As per claim 3, Greene discloses the method of claim 1, where the medical device is an infusion pump (Greene; col. 6, lines 6-23).

D. As per claim 4, Greene discloses the method of claim 1, where the step of inputting into the first computer includes converting a signal generated by an input device to a computer readable medium format (Greene; col. 1, lines 46-63, col. 2, lines 5-12, col. 8, lines 37-54 and Fig. 5).

- E. As per claim 5, Greene discloses the method of claim 1, where the first computer is at a central location (Greene; col. 7, lines 30-47).
- F. As per claim 7, Greene discloses the method of claim 1, where the first patient identifier is one of a group of identifiers, where the group of identifiers consists of: a patient name, a patient social security number, a patient blood type, a patient address, a patient's allergy, a hospital patient ID number, a hospital bed location, and a name of a patient's relative (Greene; col. 10, line 60 to col. 11, line 3).
- G. As per claim 8, Greene discloses the method of claim 1, where the operating parameter is one of a group of operating parameters, where the group of operating parameters consists of: a medication flow per unit of time, a quantity of medication, a dosing unit, a dosing duration, a dosing volume, a drug name, a dose unit, and a monitoring limit (Greene; col. 11, lines 40-51).
- H. As per claim 9, Greene discloses the method of claim 1, where the step of inputting into a second computer from a first source includes converting a signal generated by an input device to a computer readable medium format (Greene; col. 1, lines 46-63, col. 2, lines 5-12, col. 8, lines 37-54 and Fig. 5).
- I. As per claim 10, Greene discloses the method of claim 1, where the first source is a wristband (Greene; col. 1, lines 53-63, col. 5, lines 42-45 and Fig. 3).
- J. As per claim 11, Greene discloses the method of claim 1, where the first source is one of a group of first sources, where the group of first sources consists of: a bar code, a bar code reader, a wristband, a tag, a drug label, laser readable

data, a camera-type bar code reader, an RFID reader, a magnetic stripe reader, and radio-frequency readable data (Greene; col. 1, lines 53-63, col. 5, lines 42-45 and Fig. 3).

K. As per claim 14, Greene discloses the method of claim 1, where the second source is a medication label (Greene; col. 14, lines 13-30).

L. As per claim 15, Greene discloses the method of claim 1, where the second source is one of a group of second sources, where the group of second sources consists of: a bar code, a bar code reader, a wristband, a tag, a medication label, laser readable data, and radio-frequency readable data (Greene; col. 1, lines 53-63, col. 5, lines 42-45 and Fig. 3).

M. As per claim 16, Greene discloses the method of claim 1, where the medication identifier includes one of a group of medical identifiers, where the group of medical identifiers consists of: a drug name, a dosage, a manufacturer, a batch, an expiration date, a National Drug Code (NDC) number, a proprietary database drug identifier, a company product code number, and a drug prescriber (Greene; col. 14, lines 13-30).

N. As per claim 17, Greene discloses the method of claim 1, further comprising the step of: sending the operating parameter to the second computer if the first and second patient identifiers are equivalent (Greene; col. 6, lines 48-67).

O. As per claim 18, Greene discloses the method of claim 1, further comprising the step of: using the operating parameter to program the medical device (Greene; col. 8, lines 37-54 and col. 12, lines 30-46).

P. As per claim 19, Greene discloses the method of claim 1, where the step of sending the medication identifier to the first computer includes the use of a wireless communication path (Greene; col. 7, lines 30-47).

Q. As per claim 20, Greene discloses the method of claim 1, where the step of sending the operating parameter from the first computer to the medical device includes the use of a wireless communication path (Greene; col. 7, lines 8-17 and 30-47).

R. As per claim 21, Greene discloses a system for operating a medical device, the system comprising:

- i. a first computer, the first computer designed to accept a first patient identifier and an operating parameter for the medical device (Greene; col. 7, lines 9-28 and 40-46);
- ii. a second computer, the second computer designed to accept a second patient identifier from a first source, the second computer designed to accept a medication identifier from a second source, the medication identifier including a third patient identifier (Greene; col. 5, lines 42-45, 62-65 and col. 6, lines 48-67),
- iii. where the second computer is designed to send the medication identifier to the first computer if the second patient identifier and the third patient identifier are equivalent (Greene; col. 6, lines 48-67);
- iv. where the first computer is designed to send the operating parameter to the medical device if the third patient identifier is equivalent

to the first patient identifier, where the operating parameter does not pass through the second computer (Greene; col. 5, lines 42-45, 62-65 and col. 6, lines 6-23).

S. As per claim 22, Greene discloses the system of claim 21, where the first computer is designed to accept a second medication identifier, where the first computer is designed to send the operating parameter to the medical device only if the first medication identifier is equivalent to the second medication identifier (Greene; col. 10, line 60 to col. 11, line 3).

T. Claims 23, 24, 26-29, and 32-34 repeat the same limitations as claims 3, 5, 7, 8, 10, 11, 14, 15 and 16 respectively, therefore they're rejected with the same reasons given above for those claims, and incorporated herein.

U. As per claim 35, Greene discloses the system of claim 21, where the first computer is designed to send the operating parameter to the medical device if the second patient identifier and the third patient identifier are equivalent to the first patient identifier (Greene; col. 6, lines 48-67).

V. As per claims 36-40, they are apparatus claims, which repeat the same limitations of claims 1-3, 17 and 18, the corresponding method claims, as a collection of elements as opposed to a series of process steps. Since the teachings of Greene disclose the underlying process steps that constitute the methods of claims 1-3, 17 and 18, it is respectfully submitted that they provide the underlying structural elements that perform the steps as well. As such, the

limitations of claims 36-40 are rejected for the same reasons given above for claims 1-3, 17 and 18.

W. As per claims 41-44, they are system claims, which repeat the same limitations of claims 1, 2, 3 and 17, the corresponding method claims, as a collection of elements as opposed to a series of process steps. Since the teachings of Greene disclose the underlying process steps that constitute the methods of claims 1, 2, 3 and 17, it is respectfully submitted that they provide the underlying structural elements that perform the steps as well. As such, the limitations of claims 41-44 are rejected for the same reasons given above for claims 1, 2, 3 and 17.

X. Method claims 45-49, 51-55, 58-61 repeat the same limitations as method claims 1-5, 7-11, 14, 16, 18 and 20 respectively, therefore they're rejected with the same reasons given above for those claims, and incorporated herein.

Y. As per claims 62-66, they are apparatus claims, which repeat the same limitations of claims 45, 47, 54, 58 and 66, the corresponding method claims, as a collection of elements as opposed to a series of process steps. Since the teachings of Greene disclose the underlying process steps that constitute the methods of claims 45, 47, 54, 58 and 66, it is respectfully submitted that they provide the underlying structural elements that perform the steps as well. As such, the limitations of claims 62-66 are rejected for the same reasons given above for claims 45, 47, 54, 58 and 66.

Z. Claims 67-71, 73-77 and 80-86 repeat the same limitations as claims 1, 2, 2, 3, 4, 5, 7, 8, 10, 11 and 14-20 respectively, therefore they're rejected with the same reasons given above for those claims, and incorporated herein.

AA. As per claims 87-91, 93-94, they are system claims, which repeat the same limitations of claims 67-70, 76, 80, and 84, the corresponding method claims, as a collection of elements as opposed to a series of process steps. Since the teachings of Greene disclose the underlying process steps that constitute the methods of claims 67-70, 76, 80, and 84, it is respectfully submitted that they provide the underlying structural elements that perform the steps as well. As such, the limitations of claims 87-91, 93-94 are rejected for the same reasons given above for claims 67-70, 76, 80, and 84.

BB. As per claims 95-100, they are apparatus claims, which repeat the same limitations of claims 1, 2, 2, 3, 2 and 18 respectively, the corresponding method claims, as a collection of elements as opposed to a series of process steps. Since the teachings of Greene disclose the underlying process steps that constitute the methods of claims 1, 2, 2, 3, 2 and 18, it is respectfully submitted that they provide the underlying structural elements that perform the steps as well. As such, the limitations of claims 95-100 are rejected for the same reasons given above for claims 1, 2, 2, 3, 2 and 18.

CC. Claims 101-103, 106 and 107 repeat the same limitations as claims 1, 2, 10, 14 and 18 respectively, therefore they're rejected with the same reasons given above for those claims, and incorporated herein.

DD. As per claims 108-110 and 113-114, they are apparatus claims, which repeat the same limitations of claims 101-103, 106 and 107 respectively, the corresponding method claims, as a collection of elements as opposed to a series of process steps. Since the teachings of Greene disclose the underlying process steps that constitute the methods of claims 101-103, 106 and 107, it is respectfully submitted that they provide the underlying structural elements that perform the steps as well. As such, the limitations of claims 108-110 and 113-114 are rejected for the same reasons given above for claims 101-103, 106 and 107.

EE. Claims 115, 116, 118, 120-124, 126-132 repeat the same limitations as claims 1, 2, 3, 7-11, and 14-20 respectively, therefore they're rejected with the same reasons given above for those claims, and incorporated herein.

FF. As per claim 117, Greene discloses the method of claim 115, where the processor is integral with the medical device (Greene; col. 7, lines 18-29 and Fig. 5).

GG. As per claims 133-137, and 139-140, they are system claims, which repeat the same limitations of claims 115, 117, 116, 118, 123, 123 and 116 respectively, the corresponding method claims, as a collection of elements as opposed to a series of process steps. Since the teachings of Greene disclose the underlying process steps that constitute the methods of claims 115, 117, 116, 118, 123, 123 and 116, it is respectfully submitted that they provide the underlying structural elements that perform the steps as well. As such, the

limitations of claims 133-137, and 139-140 are rejected for the same reasons given above for claims 115, 117, 116, 118, 123, 123 and 116.

HH. As per claims 141-145, they are apparatus claims, which repeat the same limitations of claims 115, 116, 118, 116 and 18 respectively, the corresponding method claims, as a collection of elements as opposed to a series of process steps. Since the teachings of Greene disclose the underlying process steps that constitute the methods of claims 115, 116, 118, 116, and 18 it is respectfully submitted that they provide the underlying structural elements that perform the steps as well. As such, the limitations of claims 141-145 are rejected for the same reasons given above for claims 115, 116, 118, 116 and 18.

II. Claims 146-150 and 152-154 repeat the same limitations as claims 1, 2, 3, 7, 8, 16, 18 and 20 respectively, therefore they're rejected with the same reasons given above for those claims, and incorporated herein.

JJ. As per claims 160, 161, 162 and 164, they are apparatus claims, which repeat the same limitations of claims 146, 147, 148 and 153 respectively, the corresponding method claims, as a collection of elements as opposed to a series of process steps. Since the teachings of Greene disclose the underlying process steps that constitute the methods of claims 146, 147, 148 and 153 it is respectfully submitted that they provide the underlying structural elements that perform the steps as well. As such, the limitations of claims 160, 161, 162 and 164 are rejected for the same reasons given above for claims 146, 147, 148 and 153.

KK. Claims 165-170, and 172-174 repeat the same limitations as claims 1, 3, 5, 7, 8, 10, 14, 20 and 20 respectively, therefore they're rejected with the same reasons given above for those claims, and incorporated herein.

LL. As per claims 175-178, 180-181, they are system claims, which repeat the same limitations of claims 165, 166, 168, 169, 180, 181 respectively, the corresponding method claims, as a collection of elements as opposed to a series of process steps. Since the teachings of Greene disclose the underlying process steps that constitute the methods of claims 165, 166, 168, 169, 180, 181, it is respectfully submitted that they provide the underlying structural elements that perform the steps as well. As such, the limitations of claims 175-178, 180-181 are rejected for the same reasons given above for claims 165, 166, 168, 169, 180, 181.

MM. As per claims 182-187, 189-191, they are apparatus claims which repeat the same limitations of claims 165-170, 172-174, the corresponding method claims, as a collection of elements as opposed to a series of process steps. Since the teachings of Greene disclose the underlying process steps that constitute the methods of claims 165-170, 172-174, it is respectfully submitted that they provide the underlying structural elements that perform the steps as well. As such, the limitations of claims 182-187, 189-191 are rejected for the same reasons given above for claims 165-170, 172-174.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 6, 25, 50, 72 and 119 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greene et al. (hereinafter Greene) (U.S. Patent No. 7,051,120 B2) in view of de la Huerga (U.S. Patent No. 5,960,085).

A. As per claims 6, 25, 50, 72 and 119, Greene discloses the method, system and program of claims 1, 21, 45, 67 and 108.

Greene fails to expressly teach the pharmacy computer, *per se*, since it appears that Greene is more directed to a central treatment device (controller) (Greene; col. 7, lines 18-29, 40-47). However, this feature is well known in the art, as evidenced by de la Huerga.

In particular, de la Huerga discloses a pharmacy computer (de la Huerga; col. 10, lines 45-64).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by de la Huerga with the motivation of exchanging information on administration of the medication (de la Huerga; col. 21, lines 3-26).

6. Claims 12-13, 30-31, 56-57, 78-79, 92, 104, 105, 111-112, 125, 138, 151, 155-159, 163, 171, 179 and 188 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greene et al. (hereinafter Greene) (U.S. Patent No. 7,051,120 B2), de la Huerga (U.S. patent No. 5,960,085) and further in view of Hochman (U.S. Patent Publication No. 2001/0049608 A1).

A. As per claims 12-13, 30-31, 56-57, 78-79, 92, 104, 105, 111-112, 125, 138, 151, 163, 171, 179 and 188, Greene discloses the method, system and program of claims 1, 21, 45, 67, 87, 101, 108, 115, 133, 146, 160, 165, 175 and 182.

Greene fails to expressly teach the second computer at a remote location and is a personal digital assistant, per se, since it appears that Greene is more directed to a treatment device and a transmitter, which are in communication with the central treatment device (controller) for confirming and identifying treatment delivery (Greene; col. 7, lines 18-29). However, this feature is well known in the art, as evidenced by Hochman.

In particular, Hochman discloses a second computer at a remote location and is a personal digital assistant (Hochman; par. 0019-0020).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Hochman with the motivation of the doctor identifying the patient and drug that has to be administered to this patient (Hochman; par. 0030).

B. As per claim 155, Greene discloses a system for operating a medical device, the system comprising:

- i. a digital assistant designed to read a first patient identifier, the first patient identifier being attached to a patient's body,
- ii. the digital assistant being designed to read a medication identifier at the remote location, the medication identifier including a second patient identifier and a first medical device identifier,
- iii. the digital assistant designed to read a second medical device identifier at the remote location, the second medical device identifier being affixed to the medical device, and
- iv. the digital assistant designed to trigger the transmission of an operating parameter for the medical device from a central location to a medical device, if the first patient identifier is equivalent to the second patient identifier, and if the medical device identifier and the second medical device identifier are equivalent.

Claims 155-159 repeat the same limitations as claims 1, 3, 7, 8, and 14 respectively, therefore they're rejected with the same reasons given above for those claims, and incorporated herein.

The obviousness of modifying the teaching of Greene to include a digital assistant for the first computer (as taught by Greene) is as addressed above in the rejection of claim 13 and incorporated herein.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not used prior art teach Security infusion pump with

bar code reader 6519569 B1, Patient medication IV delivery pump with wireless communication to a hospital information management system 6790198 B1, Prescription management system 5845255 A, System and method for communicating product recall information, product warnings or other product-related information to users of products 20010056359, Prescription management system 20020042726, Computerized prescription system for gathering and presenting information relating to pharmaceuticals 20020042725, Remote data collecting and address providing method and apparatus 6408330 B1, Data collection device and system 20020116509.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dilek B. Cobanoglu whose telephone number is 571-272-8295. The examiner can normally be reached on 8-4:30.

9. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3626

10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DBC

DBC
Art Unit 3626
09/13/2006

Robert Morgan
Robert Morgan
Patent Examiner
Art Unit 3626